METHOD, SYSTEM AND ALGORITHM RELATED TO TREATMENT PLANNING FOR VISION CORRECTION

BACKGROUND OF THE INVENTION

Field of the Invention

The invention is generally directed to the field of laser vision correction and more particularly to a method, system, and algorithm for aiding in the identification and selection of a treatment plan for correcting vision in a patient's eye.

Description of Related Art

Since the earliest days of photoablative laser correction of vision defects *via* procedures referred to as PRK and LASIK, these treatments and more recently, LASEK, for example, have developed in terms of accuracy and scope of application. In the early days, subjectively measured refraction was coupled with crude (by today's standards) anterior corneal profile measurements to determine a treatment ablation based upon a naïve shape subtraction model of the cornea delivered by a broad beam, fixed axis laser beam. Over the past fifteen years, more advanced lasers have been developed that employ small spots at a high repetition based according to complex shot sorting and sequencing calculations to ablate more accurately, more efficiently, and much more correctively than in the past. Advanced topography technology, wavefront aberration measurement and analysis, laser pachymetry, and other diagnostic techniques and instrumentation have driven the development of complex treatment algorithms that no longer merely correct a patient's manifest refraction to improve visual acuity, but rather to correct higher order aberrations, compensate for biodynamic responses of the eye to tissue destruction processes, compensate for thermal heating effects on the cornea due to

the bombardment by laser pulses, and adjust for ablation beam efficiency due to oblique beam placement locations. Moreover, countless nomogram adjustments are applied to treatment algorithms to account for various myopic, hyperopic, environmental, biographic, and other parameters that effect vision correction. The aimed for end result of all of this is supervision.

With the rapid advances in technology and knowledge comes concomitant challenges for the surgeon to decide which of the many available laser platforms will execute the optimum treatment plan for a particular vision defect in a uniquely characterized eye. One might reasonably conclude that the kind of applied treatment depends upon the pre-operative findings of the patient's eye, which in itself leads to a myriad of choices. For example, an eye having significant higher order aberrations may be an appropriate candidate for a customized ablation procedure based upon wavefront data. The same eye, however, could also be a candidate for a topography-driven treatment if the main aberrations are caused in the anterior corneal surface.

Regardless of skill level, the surgeon has available only a few decision criteria to decide what kind of treatment should best be applied to the patient's eye. If, for example, three treatment options are available in which one may optimize optical zone but at the expense of tissue consumption, while another may improve visual acuity but result in poor contrast sensitivity under low light conditions, and the third provide yet different tradeoffs, it quickly becomes obvious that even out of the particular treatment options available to the surgeon, only a very few can realistically be considered.

Accordingly, the inventors have recognized the need for, and advantages of, a method and system that would aid the surgeon in classifying a particular patient's eyes

and in selecting a treatment plan based upon a review of a multiplicity of viable treatment plans that can automatically and simultaneously be computed, optimized, and displayed to the surgeon for review and selection. Thus, there is a recognized need for a solution to the problems discussed hereinabove and related thereto which are advantageously addressed by the instant invention set forth in the following description and the appended claims.

SUMMARY OF THE INVENTION

The invention is directed to a system and methods for automatically determining a multiple number of viable treatment plans for correcting a patient's vision *via* photoablative refractive surgery. Embodiments of the invention rely on selected various diagnostic input about the patient's eye to classify the eye as being particularly suitable for treatment by several different treatment algorithms selected from a larger group of available treatment algorithms. The invention is further directed to the simultaneous presentation of various treatment plans based upon selected input data and available treatment algorithms that can be reviewed, modified, and ultimately selected by the surgeon for application to the patient's eye.

An embodiment of the invention is an algorithm to aid the surgeon in the selection of a treatment plan for vision correction in a patient's eye. The algorithm includes the steps of acquiring selected diagnostic input data types about the patient's eye, parameterizing the input data to automatically classify the patient's eye into one of several pre-determined classification sets, automatically determining two or more viable treatment algorithms suitable for correcting the patient's vision defects based upon the

classification of the patient's eye, and presenting two or more corresponding treatment plans to the surgeon for prospective selection of one of the treatment plans.

The initial treatment algorithm calculations are based upon outcome determinative default parameters. In an aspect of the embodiment, the surgeon may selectively modify any or all of the default parameters and review re-calculated treatment plans, one of which may be selected to correct the patient's vision.

The diagnostic input data may include wavefront data, topography data, pachymetry data, refraction data, or other selected diagnostic information that is utilized either alone or in mutual combination by a variety of available treatment algorithms to treat the defects of the particularly classified eyes. In an exemplary aspect of the invention, the classification sets include virgin eyes versus previously treated eyes, regular eyes versus irregular eyes, and myopic and/or hyperopic eyes with or without mixed astigmatism. It will be appreciated that the invention is not limited to these exemplary classifications.

Another embodiment of the invention is directed to a method for aiding a surgeon in the selection of a treatment plan for correcting vision in a patient's eye. The method includes the steps of obtaining selected input diagnostic information about the patient's eye, analyzing the input diagnostic information to automatically determine two or more potentially usable treatment algorithms that are selected from an equal or larger number of available treatment algorithms, processing the potentially usable treatment algorithms using pre-set outcome determinative default parameters, presenting a number of viable treatment plans to the surgeon for review corresponding to the potentially usable treatment algorithms, selectively modifying one or more of the default parameters and

other defined treatment parameters, re-processing the two or more potentially usable treatment algorithms using the modified parameters, and re-presenting to the surgeon for further review the corresponding treatment plans for correcting the patient's vision based upon the diagnostic input information.

In an aspect, the method further includes selecting one of the treatment plans for application to the patient's eye.

In another aspect, information in the calculated treatment plans can be optimized and sorted to allow the surgeon to compare the multiple viable treatment plans based upon the surgeon's preferred criteria.

In another aspect, the method includes the step of automatically recommending a preferred treatment plan or, alternatively, warning against contraindicated treatment plans.

In both of the foregoing process embodiments, the selection, processing, storage, and modification of various diagnostic, biographic, and therapeutic information, as well as the display and selection of viable treatment plans is accomplished through a multilevel graphical user interface (GUI).

A system embodiment according to the invention includes a component for receiving the diagnostic input data about the patient's vision, for analyzing the input data and determining the potentially usable treatment algorithms from a database comprising an equal or larger number of available treatment algorithms, and for processing the potentially usable treatment algorithms based upon the input data; and a component for displaying the multilevel graphical user interface which facilitates review, modification, and selection of viable treatment plans for correcting the patient's vision. The system is

further operably associated with a storage medium for storing calculated and selected treatment plans which include executable instructions for a photoablative laser component of the system to deliver a selected treatment plan to the patient's eye. In an aspect, the receiving component is one of a variety of computing platforms well known in the art; the display component is a display monitor; the storage component is any of a variety of well known storage media including diskettes, CDs, DVDs, and the like; and the laser component is a 193nm excimer laser or other suitable laser for ablating corneal tissue. In an aspect, an eyetracker system and/or a microkeratome device and/or other diagnostic or therapeutic components are in operable communication with the laser system.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic flow diagram of an algorithm for classifying a patient's eye for aiding in the selection of a treatment plan for vision correction in a patient's eye according to an embodiment of the invention;

Fig. 2 is a schematic flow diagram of a method for aiding in the selection of a treatment plan for vision correction in a patient's eye according to another embodiment of the invention;

Fig. 3 is a schematic representation of a system used for planning a treatment for vision correction in a patient's eye according to an embodiment of the invention;

Fig. 4 is a schematic representation of a process step set forth in Fig. 2;

Fig. 5 is a schematic representation of another process step set forth in Fig. 2;

Fig. 6 is a view of a start-up display screen of a graphical user interface (GUI) according to an embodiment of the invention;

Fig. 7 is a view of another display screen of the GUI according to an embodiment of the invention;

Fig. 8 is a view of another display screen of the GUI according to an embodiment of the invention;

Fig. 9 is a view of another display screen of the GUI according to an embodiment of the invention;

Fig. 10 is a view of another display screen of the GUI according to an embodiment of the invention;

Fig. 11 is a view of another display screen of the GUI according to an embodiment of the invention;

Figs. 12a,b are views of a preferences display screen of the GUI according to an exemplary embodiment of the invention;

Fig. 13 is a view of a patient selection display screen of the GUI according to an exemplary embodiment of the invention;

Fig. 14 is a view of a patient information display screen of the GUI according to an exemplary embodiment of the invention;

Fig. 15 is a view of a treatment overview display screen of the GUI according to an exemplary embodiment of the invention;

Fig. 16 is a view of an illustrative treatment option display screen of the GUI according to an exemplary embodiment of the invention;

Fig. 17 is a view of another illustrative treatment option display screen of the GUI according to an exemplary embodiment of the invention;

Figs. 18a,b,c are views of a data ckeck display screen of the GUI according to an exemplary embodiment of the invention; and

Fig. 19 is table of parameter value ranges according to an exemplary embodiment of the invention.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT OF THE INVENTION

To assist the reader in a clear understanding of the invention, certain terminology used throughout the description of the invention will be understood to have the following meanings: In the field of refractive laser vision correction, a treatment algorithm is understood as the process calculation for determining certain parameters of a particular type of treatment. For example, for a laser ablation treatment to correct a myopia refractive error, a desired or target corneal profile will be determined as well as the number, sequence, and placement of laser shots on the pre-operative corneal surface to obtain the target profile. The laser shot placement, sequence, and number calculations are parameters used to calculate a shot file, referred to herein as a ".TLS file," which stands for Technolas Laser Session. A laser used to apply the ablative photorefractive treatment uses the shot file as its executable instruction to carry out the particular treatment. A treatment plan as that term is used herein represents the process planning and result of processing a particular treatment algorithm based upon defined parameters and determining a prospective outcome represented by a variety of information that may include algorithm parameters as well as simulated post-operative maps, simulated

ablation profiles, pachymetry data, optical zone dimensions, refraction values, aberration information, topography information, vision metric indicators, and other relevant information, including the shot file. Further as used herein, with respect to eye classification, a virgin eye means an eye that has not had prior corneal refractive surgery; a regular eye refers to an eye having associated vision defects that are correctable with standard ophthalmics such as spectacles, contact lenses, and the like, or by non-customized photoablative surgery limited to sphere and cylinder correction, whereas an irregular eye will be, for example, a keratoconic eye or an eye that cannot typically be characterized by wavefront measurements, but rather requires topographic or other gross analyses. Myopic, hyperopic, and astigmatic eyes have their typical meanings as well understood in the art.

Fig. 1 illustrates an algorithm 100 to aid in the selection of a treatment plan 190 for vision correction in a patient's eye. At step 110 a variety of types of diagnostic input data 110_a, 110_b, 110_c, 110_d ... 110_n that has been acquired is provided as input to the processing software. These diagnostic data types include, for example, wavefront data, topography data, pachymetry data, refraction data, and other data types that a person skilled in the art could utilize to characterize a patient's eye and its vision defects. All, or only some, or various combinations of the data may be acquired and/or used as will be determined by the various treatment algorithms. At step 120 the diagnostic input data 110_n is parameterized so that the patient's eye can be classified into one of a pre-determined number of classification sets designated, for illustration purposes only, as Type A 135, Type B 140, Type C 145, and Type D 150. In an aspect according to the invention, the classification types are determined to be virgin eyes versus previously

treated eyes, regular eyes versus irregular eyes, myopic eyes with or without astigmatism, particularly mixed astigmatism, and hyperopic eyes with or without simple and/or mixed astigmatism, as these terms have been defined hereinabove. It will be understood that the particular listed classification types correspond to types of eyes and/or vision defects associated with particular treatment algorithms that typically are proprietary to a supplier. For example, a treatment algorithm known to those skilled in the art as a Planoscan® treatment (Bausch & Lomb Incorporated, Rochester, New York) might be used to treat a regular, myopic or hyperopic eye using a Technolas 217® laser system (Bausch & Lomb Incorporated, Rochester, New York). Or, for example, a topographically driven treatment algorithm such as referred to in U.S. Patent No. 5,891,132 may suitably be used to treat an eye determined to be irregular by topographic diagnostic input data. In another example, an eye classified as having measured higher order aberrations and a regular topography might be a preferred candidate for a custom Zyoptix® treatment algorithm (Bausch & Lomb Incorporated, Rochester, New York). According to an exemplary embodiment of the invention, and as known in the art, it can be determined whether an eye has previously had photoablative laser surgery by looking at topographic and pachymetric diagnostic information; for example, by analyzing anterior surface topography and delta-pachymetry measurements, the presence and location of a transition zone in the previously ablated cornea can be determined. The irregularity of an eye for purposes of classification can be determined, for example, by examining the symmetry (dipole) of the corneal topography or decentration. Wavefront measurement and analysis, manifest refraction, and other techniques known to those skilled in the art can be used to determine the sign and magnitude of defocus and cylinder errors and higher

order aberration information. Using these types of information to classify a patient's eye helps to identify which treatment algorithm(s) might be appropriate for developing a treatment plan to correct the patient's vision defect. Illustratively, a regular topography and a low wavefront measurement may indicate that a standard ablation is the suitable treatment. A regular topography and a high wavefront measurement may indicate that a customized or semi-customized wavefront-based treatment is most appropriate. An irregular topography plus a high wavefront measurement (i.e., highly aberrated cornea) may indicate that a topographically-based treatment or a hybrid-driven treatment should be considered. In this aspect, higher-order corneal aberrations, rather than the higher-order aberrations of the entire ocular system, are addressed. Irregular topography with or without a high wavefront measurement may contraindicate refractive surgery, suggesting instead spectacle or other ophthalmic lens correction, or ophthalmic surgical correction such as a corneal transplant, for example. Having thus described particular diagnostic types, eye classification types, treatment algorithm types, and so on, it is to be understood that the invention is in no way limited by the foregoing examples.

At step 130 all of the viable treatment algorithms 160_{a-n} for the particular eye classifications are determined from a pre-programmed database of all available treatment algorithms 165_{a-n}. For example, the patient's eye may be classified by refraction as a Type A having typical myopia with astigmatism, that may suitably be treated by treatment algorithm 160_e or treatment algorithm 160_n. At step 170, a multiple number of treatment plans 190_{a-n} are presented in the form of a display to be discussed in greater detail below, that respectively correspond to the appropriately identified treatment

algorithms 160_{a-n} using pre-programmed default parameters which are outcome determinative of the algorithms.

The multiplicity of treatment plans 190_{a-n} based upon the default parameters and the diagnostic input data will be presented to the surgeon *via* a display screen in the form of a multi-level graphical user interface (GUI) 312-316 illustrated by examples in Figs. 6-11. According to the invention, the surgeon then has the option to a) review the various treatment plans (190_{a-n}) that have been presented, b) save these to a storage medium (282), c) select one of the treatment plans (190_x) for prospective application, or d) modify (step 168) selected parameters and be presented with re-calculated treatment plans ($190'_{a-n}$), as will be described in greater detail below in respect to a related embodiment according to the invention.

Another embodiment according to the invention is now described with reference to Figs. 2-11. Fig. 2 diagrammatically sets forth a method 200 for aiding the selection of a treatment plan 290_x for correcting vision in a patient's eye. At step 210, selected pre-operative diagnostic data 210_{a-n} that has been obtained is provided to a calculation module 310 (Fig. 3) where, at step 220 it is analyzed to determine a multiple number of potentially usable treatment algorithms 260_{a-n} selected from a database containing an equal or larger number of available treatment algorithms 265_{a-n} which are initially programmed with certain outcome determinative default parameters to allow first-run calculations. As described above, the analysis of particular diagnostic data 210_{a-n} will inform the selection of particular treatment algorithms 260_{a-n}, leading to available treatment plans 290_{a-n}. According to the invention, this association is done automatically for all potentially usable treatment algorithms selected from a database of all available

algorithms 265_{a-n}. At step 230 the calculation module processes the potentially usable treatment algorithms 260_{a-n} utilizing various outcome determinative default parameters; for example, LASIK flap thickness, residual stromal tissue depth, optical zone size, and/or others to determine the corresponding plurality of treatment plans 290_{a-n}. These various treatment plans are displayed to the surgeon at step 270 on a display device 370 (Fig. 3) by means of the multi-level graphical user interface (GUI) 312 (Fig. 6) and illustrated in various display formats 313-316 in Figs. 7-11.

In Fig. 7, for example, four treatment plans 290_{a-d} representing a Zyoptix® A treatment algorithm, a Zyoptix B treatment algorithm, a Zyoptix C treatment algorithm, and a Zyoptix D treatment algorithm are illustrated on a GUI treatment review display 313. Each treatment plan 290_n contains a variety of information about the treatment including simulated ablation profile maps, various diagnostic measurements such as optical zone diameter and pachymetry, number of laser ablation shots and ablation depth for each treatment algorithm, and other information as can be seen in Fig. 7. In the exemplary embodiment of Fig. 7, for all of the treatments information is provided about pachymetry, subjective refraction, treatment refraction, number of laser pulses, treatment time, maximum ablation (μm), remaining stroma (μm), and optical zone diameter (mm). For the Zyoptix A and B treatment plans, information is presented regarding higher order aberrations over a 6mm pupil diameter, objective manifest refraction (sphere, cylinder, axis), pupil diameter (mm) for the calculated objective manifest refraction, and central ablation depth (μm). For the Zyoptix C and D treatment plans, the presented information includes pre-operative K-readings in diopters (D), pre-operative conic constants (Q), treatment pre-operative K-readings (D), and target post-operative conic constants (Q').

As will be discussed further below, the exemplary treatment review screen 313 in Figure 7 may color-code treatments that are recommended or contraindicated, as well as provide textual information as to why a particular treatment plan should or should not be used. The screen provides an editable field for "pachymetry," "flap thickness," and "optical zone" to allow adjustment of these values for all of the displayed treatments. Default values may also be restored for the above editable fields. Selectable information is provided relating to the software version of the system, and diagnostic wavefront and topography files with associated comments. A selectable item for rotational eye tracking information relating to pupil shift and pupil rotation is further provided. Recalculation of the available treatment plans based upon user input changes are calculated from this display screen. Treatment plans and associated graphical maps can be maximized as illustrated by the display screens in Fig. 11. Hint boxes can be displayed for each of the treatment plans based on cursor placement; for example, under Zyoptix A: "wavefront-based treatment with enhanced asphericity for myopia" (Zyoptix personalized aspheric treatment mode); Zyoptix B: "wavefront-based treatment" (Zyoptix personalized treatment mode); Zyoptix C: "aspheric treatment with reduced ablation depth" (Zyoptix aspheric tissue saving treatment mode); and Zyoptix D: "treatment with reduced ablation depth" (Zyoptix tissue saving treatment mode). The exemplary treatment review screen GUI will facilitate execution of storage and selection commands as well as display warning messages based upon modified default parameters. This screen further allows the export of the selected and calculated treatment to an executable .TLS file for laser application. Commands for optimization of the optical zone and other optimization/sorting functions are also executed from this screen.

Due to the fact that each of the calculated treatment plans 290_{a-d} are based on default parameters that represent required initial input for the treatment algorithms, the method according to the invention provides for user selective modification of one or more of the default parameters and/or other defined treatment parameters at step 275 as illustrated by GUI screen display 314 in Fig. 8, accessed by a pull-down menu. The user can then request re-processing of the treatment algorithms shown at step 230' in Fig. 2 whereupon re-calculated treatment plans 290' are re-displayed at step 270'. The re-calculated treatment plans $290'_{a-d}$ appear as illustrated again by 313 in Fig. 7. This type of iteration can occur as many times as the surgeon feels is necessary, but a single iteration will likely be sufficient in most cases.

In an aspect according to this embodiment, the user can save the calculated treatment plans at step 280 in a storage medium 282 (Fig. 3) that is readable or has means making it readable by a therapeutic component 294 such as an excimer laser used to apply the ultimately selected treatment plan 290_x. As described above, each stored treatment plan 290_{a-n} will ultimately contain a shot file 399 which is the executable instruction carried out by the therapeutic laser component to apply the desired photoablation treatment to the eye. Prior to saving at step 280, the GUI displays a data check screen at step 279 as illustrated by displays 315a,b in Figs. 9A and 9B for two different patients. Each data check screen 315 contains information based upon the calculated and selected treatment plans. In a first exemplary embodiment illustrated in Fig. 9B, the data check screen 315b contains the following information: patient name, patient date of birth, patient eye, treatment algorithm type, selected treatment sphere, selected treatment cylinder, selected treatment axis, optical zone size, treatment zone,

number of laser pulses, treatment time, maximum ablation depth, remaining pachymetry under the flap for the specified flap thickness (LASIK), currently running software version, calculation date, diagnostic exam dates, instrument-specific pachymetry information, manifest refraction, and laser shot frequency. In another exemplary embodiment illustrated in Fig. 9A, the information in the data check screen 315a includes objective manifest refraction, central ablation depth, wavefront RMS values at 6mm pupil diameter, rotational eyetracker data (if used), and a text message such as "recommended centration of treatment is the pupil center". In a third exemplary embodiment for particular treatment plan types, the data check information consists of corneal curvature information (K-readings) and pre- and post-operative conic shape profiles (Q-factors).

Once the suitable treatment plans are saved at step 280, a treatment plan 290_x is selected at step 292 for potential application at step 296.

Another aspect of the GUI display structure and function is a preference screen 316 illustrated in Fig. 10 that is also accessed *via* a pull-down menu. In an exemplary embodiment, the preference screen allows: (a) default nomogram values to be set for all different treatment options; (b) the setting of a default assumed flap thickness (LASIK) for the different treatment options; (c) setting of a default optical zone diameter for different treatment options; (d) the setting of limit values for maximum ablation, treatment time, number of laser pulses, minimal optical zone size, minimum post-operative K-reading, maximum post-operative K-reading, and minimum remaining stromal thickness under the flap (LASIK); and (e) a fixed amount of over or under

correction can be set as a nomogram value for a particular treatment (e.g., add 0.5D to the sphere for all Type A treatment plans).

In another aspect, with reference to Fig. 4, the surgeon may wish to re-evaluate the available treatment plans based upon certain optimized parameters. For example, for the Zyoptix A-D treatment plans illustrated in Fig. 7, it may be desirable to view all of the treatment plan information based upon the optimization of optical zone (OZ) diameter. In the treatment review screens 313 illustrated in Fig. 7, for example, an input to optimize the OZ is provided. When executed, the optical zone is increased for all available treatment plans until the minimum residual stromal depth under the flap (LASIK) is equal to a user-defined limit, to the extent allowable based upon diagnostic wavefront input data for example. At step 250 in Fig. 2, optimization and sorting illustrated by OZ 252_a, residual stromal depth 252_b, and refraction 252_c can be calculated and treatment plans re-displayed at step 270" as shown in Fig. 4.

In another aspect, the number of potentially useable treatment algorithms 260_{a-n} is at least two selected from a larger group of available treatment algorithms 265_{a-n} (Fig. 2) preferably directed to myopia treatment only, hyperopia treatment only, myopia with astigmatism, hyperopia with astigmatism, other standard lower order aberration correction, higher order aberration correction, re-treatment correction, spherical corrective treatment with reduced tissue ablation, aspheric corrective treatment with reduced ablation volume, LASIK treatments, LASEK treatments, PRK treatments, nomogram adjusted treatments, and other customized treatments. The invention, however, is not so limited.

In another aspect according to an embodiment of the invention, the system may be programmed to automatically recommend a preferred treatment plan to the user. This option could be implemented by color-coding the preferred treatment plan out of the available treatment plans as illustrated by 317 in Fig. 11.

Based upon the nature of the treatment plan, certain other default data, preference data, warning information, and other outcome determinative parameters may be made accessible through the GUI menus. For example, the calculation of certain treatment plans for the correction of aspherical aberrations may require the input of rotational eyetracker information. LASIK-based treatments may require particular microkeratometric information.

A system embodiment 300 according to the invention is schematically illustrated in Fig. 3. Diagnostic input 210_n can be obtained by various topography devices, wavefront sensors, pachymetry devices, phoropters, customized diagnostic instrumentation, and other ophthalmic devices and techniques that are not in and of themselves parts of the invention *per se*. The means 310 for receiving the diagnostic input data, for analyzing the input data and determining the potentially usable treatment algorithms, and for processing the potentially usable treatment algorithms based upon the input data and other algorithm outcome determinative parameters can be a software-driven calculation module such as a P.C. or other well-known form of a computing platform. The display means 370 is typically a screen or monitor well known in the art, which is used to display the graphical user interface 312 (and associated display screens and functions) as described hereinabove. Once it is determined what functions and attributes are to be provided by the GUI according to the embodiments of

the invention, it is well within the skill in the art of computer programming to create the appropriate GUI displays and calculation processes. A device-readable storage medium 282 will typically be a computer diskette, floppy disk, CD, DVD, computer hard drive, or electromagnetic carrier wave which can store the data in appropriate file form and which is readable by a computer or control component of the therapeutic laser component 294 of the system to execute the shot (.TLS) file 399 for applying the selected treatment plan 290_x. The photoablative laser component 294 will typically be an excimer laser emitting light having a wavelength of 193nm or other suitable gas medium or solid state laser device adapted for corneal tissue photoablation.

Another exemplary embodiment according to the invention is illustrated by a treatment planning software calculation program (referred to hereinafter as "Treatment Planner") that generates an individual treatment file for a patient on the basis of the available measured data from diagnostic wavefront sensing measurements and diagnostic corneal topography and pachymetry measurements. In an exemplary aspect, the diagnostic information is accessed by a Zyoptix® Diagnostic Workstation (Bausch & Lomb Incorporated, Rochester, New York). This workstation is a combination Zywave II Aberrometer and Orbscan IIz Anterior Segment Analyzer. Zywave (aberrometer) data is stored in what are referred to as ".ATE" (i.e., Aberrometer Technolas Export) files, and Orbscan (corneal) data is stored in ".OTE" (i.e., Orbscan Technolas Export) files. The subsequently calculated treatment data is stored in the ".TLS" file, described above, which forms the basis for the refractive laser ablation treatment. According to an exemplary aspect, the treatment is known in the art as a Zyoptix vision correction

treatment, which is carried out with a Technolas 217z excimer laser system operating at 100Hz.

According to the exemplary embodiment, the Treatment Planner calculation software is utilized by selection from a Windows® computer screen icon, which directs the user to the main screen display 312 as shown in Fig. 6. The user can click on the icon 3002 labeled "Preferences" to preset settings such as, for example, the file path for the wavefront diagnostic (.ATE) files, the corneal (.OTE) diagnostic files, and the treatment data (.TLS) files; a language preference; clinic information such as clinic name, laser serial number, surgeon name(s) and technician name(s). The Preferences screen also allows certain default settings to be preset; for example, LASIK flap thickness; K-reading; Q-value (e.g. Q, Q'), which represent a pre-operative aspheric corneal shape factor and a post-operative aspheric corneal shape factor, respectively; OZ (optical zone); OZ calculated from pupil size; and nomograms representing a percent of baseline refraction values. (K-reading is the central corneal curvature calculated on the basis of corneal elevation measurements and is expresses in diopter units as (n-1)/R, where R is the radius of the eye). The interested reader is referred to U.S. Application Serial No. 10/460801 entitled BICONIC ABLATION WITH CONTROLLED SPHERICAL ABERRATION, filed on June 12, 2003 and incorporated herein by reference in its entirety to the fullest extent allowed by applicable laws and rules. Said application relates to an ablation treatment plan for an aspheric tissue saving mode that may be one of the treatment modes of the instant invention embodiment.

Illustrative display screens 1202a, 1202b of the aforementioned Preference settings are shown in Figs. 12a and 12b, which correspond, respectively, to the displays

314, 316 illustrated in Fig. 8 and Fig. 10 for an exemplary embodiment described earlier herein. The user then has the option to save the Preference settings and go on to the calculation phase of the Treatment Planner program, or return to the main menu.

According to this exemplary embodiment, patient selection and treatment calculation is begun by activating the "Select Patient" icon 3004 on the main menu screen 312 shown in Fig. 6. When the Select Patient icon is activated, a display screen 1302 as shown in Fig. 13 is presented. The diagnostic files located in the folders specified in the Preference section, described above, are displayed, sorted by .OTE (corneal diagnostic data) files 1310 and .ATE (wavefront diagnostic) files 1312 separately. As shown, the displayed data includes windows 1304 for the patient's last and first names, a window 1306 for the eye (OS or OD) in question, and a window 1308 for the date and time of data acquisition. It will be appreciated that other arrangements and content of stored and displayed information may be presented depending upon a variety of factors known to those skilled in the art. In an exemplary aspect, selection of the .OTE or .ATE file will present additional data 1316 in each file that may help to clearly identify a patient or a specific measurement; for example, date of birth, refractive values, file name, etc. In another aspect, specific files can be searched by using the patient search area 1304 shown on the display by entering the name of a patient whose data has previously been saved or, in another example, by scrolling through a list of patient names and selecting the desired patient.

In an alternative aspect, a user may wish to directly calculate a treatment based on subjective refraction in which case neither the .ATE nor the .OTE files will be used. A "New Patient" icon 1318 can then be selected, which brings up a patient information

screen 1402 as illustrated in Fig. 14. Basic patient information can be viewed and verified, modified or entered in the patient information screen 1402. In an exemplary aspect, the following data are displayed in the patient information window: patient ID; patient last name; patient first name; date of birth; gender; eye (OD/OS); re-treatment; subjective refraction (sphere, cylinder, axis); PPR (Predicted Phoropter Refraction; i.e., objective manifest refraction values based on .ATE file data; see application serial number 10/100782 entitled OBJECTIVE MEASUREMENT OF EYE REFRACTION filed on March 18, 2002 and incorporated herein by reference in its entirety to the fullest extent allowed by applicable laws and rules); pachymetry (from .OTE file or based on an ultrasound diagnostic measurement or other suitable diagnostic measurement); and pupillometry. In an exemplary aspect, the allowed pupil diameter range is 4mm to 11mm. In an exemplary aspect, input values that have been modified may appear in a different color or be otherwise distinguished for screen viewing. The user may then verify the data and continue on to treatment calculation or return to a previous screen for data re-entry or cancellation. In an exemplary aspect, a warning message (not shown) will be displayed if a required entry or an input value is outside of a predetermined default range.

According to the instant exemplary embodiment, two treatment options are available to the user. They are referred to herein as the Zyoptix Personalized Treatment algorithm and the Zyoptix Tissue Saving algorithm. The Zyoptix Personalized Treatment calculation option is a wavefront optimization treatment based on wavefront information data (.ATE files) and corneal topography data (.OTE files). In an exemplary aspect, the Personalized Treatment mode supports calculation of myopic and hyperopic

treatments. According to this aspect, the sphere and cylinder of treatment refraction are user modifiable variables. The treatment refraction is expressed in a percentage of the PPR. The percent value is a user modifiable variable. The optical zone (OZ) of the treatment is also a user modifiable variable. The Personalized Treatment option algorithm is based upon the optimized placement of 2mm and 1mm laser spots on the corneal stroma provided, for example, by the Technolas 217z laser system. Treatment is centered over the pupil center. In this aspect, the Personalized Treatment option supports iris recognition parameters such as cyclotortion and pupil center shift, for example.

The Zyoptix Tissue Saving treatment calculation is based on measurements of subjective refraction, keratometric values (K-readings) and optical zone. In an exemplary aspect, this treatment option uses a combination of 2mm and 1mm truncated Gaussian beams for ablation, and has demonstrated tissue saving for myopic treatments compared to Planoscan treatments, which use a 2mm hard top beam profile, as those skilled in the art will understand. An amount of tissue saving may also be achieved over the Personalized Treatment option described above due to the fact that small deformations of the optical system, known as higher order aberrations, are not attempted to be corrected in this mode. Compared to the Planoscan algorithm, which assumes an average normalized shape for the preoperative cornea (K=43.3D), the actual curvature value for the corneal steepness (K-reading) can be included in the Tissue Saving treatment mode either by importing the value form the .OTE file, entering a K-value, or using a default value K= 43.3D. Treatment in this mode may be centered at the pupil center or, alternatively, toward the Purkinje reflex at the discretion of the surgeon. In the exemplary embodiment, the .ATE file has no influence on this treatment mode. In a

related alternative aspect, an aspheric tissue saving treatment could be selected by using selected pre- and post-operative aspheric corneal shape factors, Q, Q′. In this aspect, conical surface could be determined according to the equation:

$$Z = \frac{p^2}{R + \sqrt{[R^2 - (1+Q)p^2]}}$$

Where

Z is the sag of the conical surface,

$p^2 = x^2 + y^2$,

R = central radius of curvature, and

$-1 \leq Q \leq 1$ ($Q \neq 0$), where the surface can be a prolate or oblate ellipsoid, a parabola, or a hyperbola. In an aspect of this embodiment, the conic constants Q (and Q′) define biconic surfaces; i.e., Q (and Q′) and the central radius of curvature, R (and R′), are functions of x, y, and may be different in the x and y directions. A biconic surface allows specification of R_x, R_y, Q_x, Q_y (as well as their respective post-operative values) directly. As those skilled in the art will understand, the sag, Z, of a biconic can be expressed as

$$Z = \frac{c_x x^2 + c_y y^2}{1 + \sqrt{[1-(1+Q_x)c^2{}_x x^2 - (1+Q_y)\, c^2{}_y y^2]}}$$

where $c_z^{\text{biconic}} = \dfrac{-\underline{s}_x c_x x^2 - \underline{s}_y c_y y^2}{c_x x^2 + c_y y^2}$

and $R_z^{\text{biconic}} = \dfrac{+ c_x x^2 + c_y y^2}{- \underline{s}_x c_x x^2 - \underline{s}_y c_y y^2}$

and $\underline{s}_x = -(1+Q_x)$, $\underline{s}_y = -(1+Q_y)$

so that $-z^2 c_z^{\text{biconic}} = -2z + (c_x x^2 + c_y y^2)$.

Substituting $z = z' + R_z^{\text{biconic}}$

then, $c_x x^2 + c_y y^2 + c_z^{\text{biconic}} z'^2 = 1/ c_z^{\text{biconic}}$

and since $c_x = 1/R_x$, $c_y = 1/R_y$,

then $x^2/R_x + y^2/R_y + z'^2/ R_z^{\text{biconic}} = R_z^{\text{biconic}}$.

Employing the definitions $c_z = \frac{-s_x c_x - s_y c_y}{2}$

and $\Delta = \frac{-s_x c_x + s_y c_y}{2}$

gives (in series expanded form) $c_z^{\text{biconic}} = \frac{-s_x c_x^2 x^2 - s_y c_y^2 y^2}{c_x x^2 + c_y y^2}$

$$= \frac{c_x(c_z + \Delta)x^2 + c_y(c_z - \Delta)y^2}{c_x x^2 + c_y y^2}$$

$$= c_z - \frac{\Delta(c_x x^2 - c_y y^2)}{c_x x^2 + c_y y^2}.$$

Depending on the treatment parameters, three different options of a treatment calculation screen may be presented to the user in an exemplary aspect. First, a treatment overview screen 1502 as shown in Fig. 15 is presented if both .OTE and .ATE files have been selected and more than one treatment option is available. From the treatment overview screen 1502, the user can either go straight to the calculation screen for one of the available treatment modes, or the user can perform a simultaneous calculation of the two displayed treatment modes, which allows a direct comparison of the results as displayed in the treatment overview window. As shown on screen 1502, the display parameters 1504 include (in addition to what is described in the individual calculation screens, described below) Z400 (Zernike spherical aberration coefficient) at 6mm, the conic constant, Q, at 6mm pupil diameter derived from the topography data, and a mean K-reading at 6mm pupil diameter derived from the topography data of the .OTE file. Input parameters 1506 include optical zone and flap thickness. Calculated output parameters 1508 include maximum ablation, central ablation, residual stroma (estimated

or calculated), treatment zone, amount of pulses and treatment time. Alternatively, a Tissue Saving calculation screen 1602 as shown in Fig. 16 will display if only the .OTE file was selected, if neither the .OTE nor the .ATE files were selected, or if the .OTE and the .ATE files were selected but the personalized treatment mode is not available for the selected patient. The third alternative option is the display of a Personalized calculation screen 1702 as show in Fig. 17. This screen is displayed if the Personalized mode is selected or if the Tissue Saving mode is not available for the selected patient.

As illustrated in Fig. 16, the tissue saving calculation screen 1602 includes display parameters 1604 relating to pachymetry, pupillometry, and subjective refraction; input parameters 1606 include K-reading, treatment refraction, percent of subjective refraction, optical zone and flap thickness. Primary output parameters 1608 include maximum ablation, estimated residual stroma, treatment zone, number of pulses and treatment time. In various aspects, the estimated residual stroma thickness is based on an entered pachymetry value minus an entered flap thickness value minus a calculated maximum ablation value; alternatively, an estimated residual stroma value is based on pachymetry map data, entered flap thickness and the calculated ablation profile; alternatively, a more accurate (albeit, more time consuming) calculation of residual stroma can be selected if desired. A calculation icon 1612 is provided close to the estimated residual stroma value if the user wishes to verify the calculated residual stroma thickness.

As further shown in Fig. 16, an ablation profile map 1610 is displayed on the right hand side of the screen 1602. In an aspect, a map field is provided for accessing a pull-down list of the available maps that can be viewed. For example, if no .OTE files

were loaded, no pre-op maps will be available; if a .OTE file was loaded, pre-operative maps including axial keratometric maps, anterior elevations maps, posterior elevation maps and pachymetry maps will be available. Further, if a .OTE file was loaded, simulated post-op pachymetry maps will be available. In the exemplary aspect, the map of the ablation profile is shown by default after calculation of a treatment.

Fig. 17 shows a Personalized Treatment mode calculation screen 1702. For this treatment mode, the display parameters 1704 include pachymetry, pupillometry, higher order (RMS) aberration values at a 6mm pupil diameter, wavefront diameter, subjective refraction and PPR. Input parameters 1706 include treatment refraction, percent of PPR, optical zone and flap thickness. Calculated output parameters 1708 include maximum ablation, central ablation, residual stroma (estimated or calculated as described above), treatment zone, amount of pulses and treatment time. A pull-down list of maps is, again, available. For example, pre-op maps include axial keratometric map, anterior elevation map, posterior elevation map, pachymetry map, higher order wavefront map and total wavefront map. Simulated post-op anterior elevation, axial keratometric, and pachymetry maps are also available, as well as the default ablation profile map 1710 as shown.

From any of the calculation screens the user may select an export icon 1615 that then brings up a Data Check screen 1802a,b,c as shown in Figs. 18a,b,c, respectively. The Data Check screen 1802, corresponding to a similar screen display 315a,b shown in Figs. 9a,b, for a previously described exemplary embodiment, allows the user to re-check and print the screen information before saving the .TLS (treatment) file. In addition to parameters shown either in the patient information screen or the individual calculations

screens, other relevant information is displayed in the data check screen including: amount of treatment phases, number of pulses for 2mm and 1mm beams, iris recognition data if available for the particular treatment, type of algorithm (myopia, hyperopia, mixed astigmatism) used as the basis for the calculation, refraction, type of baseline refraction, and additional information from the topography and wavefront diagnostics.

When the user is ultimately satisfied with the data and intends to perform a treatment, clicking on a Save icon 1804 creates the .TLS file, which will be saved under the file path chosen in the Preferences described herein above.

Table 1 of Fig. 19 shows an exemplary range of parameter values accepted by the software according to the exemplary embodiment of the invention.

Notwithstanding the embodiments specifically illustrated and described herein, it will be appreciated by those skilled in the art that various modifications and variations of the instant invention are possible in light of the description set forth above and the appended claims, without departing from the spirit and scope of the invention.